SECTION 5 - 510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: **K 113269**

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Date of Preparation November 2nd, 2011

Device names

REAGENT

Trade/proprietary Name:	**ELITech Clinical Systems ALP IFCC SL**
Common or Usual Name:	Alkaline phosphatase, **"ALP IFCC SL"**
Device Class	Class II
Classification name	Alkaline phosphatase or isoenzymes test system (Sec.862.1050)
Product code	CJE– Nitrophenylphosphate, alkaline phosphatase or isoenzymes

Predicate device Roche Diagnostics ALP2S (Alkaline phosphatase acc. to IFCC Gen.2) (K033185)

Device description The device for this submission is available as kit only. It consists of 2 reagents R1 & reagent R2.
Reagent R1 contains: 2-Amino-2-methyl-1-propanol (AMP) buffer (pH 10.45), Magnesium ions, Zinc ions.
Reagent R2 contains: *p*-Nitrophenylphosphate (*p*-NPP), sodium azide.

Intended Use ELITech Clinical Systems ALP IFCC SL is intended for the quantitative *in vitro* diagnostic determination of alkaline phosphatase in human serum and plasma on ELITech Clinical Systems Selectra analyzers.
It is not intended for use in Point of Care settings.

Indication for use Alkaline phosphatase or its isoenzymes measurements are used in the diagnosis and treatment of liver, bone, parathyroid and intestinal diseases.

Comparison to Predicate device

	ELITech Clinical Systems Device (ALP IFCC SL)	Predicate device (Roche Diagnostics ALPP2S (K033185)
Intended use	Intended for the quantitative *in vitro* diagnostic determination of alkaline phosphatase in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.	*In vitro* test for the quantitative determination of alkaline phosphatase in human serum and plasma on the **cobas c 111** system.
Indication for Use	Alkaline phosphatase or its isoenzymes measurements are used in the diagnosis and treatment of liver, bone, parathyroid and intestinal diseases.	Alkaline phosphatase or its isoenzymes measurements are used in the diagnosis and treatment of liver, bone, parathyroid and intestinal diseases.
Assay protocol	Colorimetric. Kinetic. Measurement of the rate of production of *p*-nitrophenol at 405 nm. Based on IFCC recommendations.	Colorimetric. Kinetic Measurement of the rate of production of *p*-nitrophenol at 409 nm. Based on IFCC recommendations.
Composition	Reagent R1: AMP buffer (pH 10.45) ; Magnesium ions 2.4 mmol/L ; Zinc ions 1.2 mmol/L ; Reagent R2: *p*-NPP 80 mmol/L ; Sodium azide < 0.1% ;	Reagent R1: AMP buffer (pH 10.5) 1.724 mol/L; Magnesium acetate 3.83 mmol/L; Zinc sulfate 0.766 mmol/L; N-(2-hydroxyethyl)-ethylenediamine triacetic acid: 3.83 mmol/L; Reagent R2: *p*-NPP 132.8 mmol/L; Preservatives
Appearance of reagents	Liquid form, ready to use	Liquid form, ready to use
Sample type	Serum Plasma	Serum Plasma
Reagent storage	Store at 2-8 °C and protect from light. The reagent is stable until the expiry date stated on the label.	Store at 2-8 °C the reagent is stable until the expiry date stated on reagent.
Expected values	Serum/plasma: Men: 20-50 years old: 53-128 U/L ≥ 60 years old : 56-119 U/L Women: 20-50 years old: 42-98 U/L ≥ 60 years old : 53-141 U/L	Serum/plasma: Adults Males (n = 221) 40-129 U/L Females (n = 229) 35-104 U/L Consensus values Males 40-130 U/L Females 35-105 U/L Children aged 1 day <250 U/L aged 2-5 days <231 U/L aged 6 days-6 months <449 U/L aged 7 months-1 year <462 U/L aged 1-3 years <281 U/L aged 4-6 years <269 U/L aged 7-12 years <300 U/L aged 13-17 years (f) <187 U/L aged 13-17 years (m) <390 U/L

	ELITech Clinical Systems Device (ALP IFCC SL)	Predicate device (Roche Diagnostics ALP2S (K033185)
Instrument	Selectra ProM Analyzer	Cobas c111
Measuring range	20 – 1023 U/L	3 – 1200 U/L
Limit of detection (LoD)	6 U/L	3 U/L
Limit of quantification (LoQ)	20 U/L	
Precision	**Within run** Level 57 U/L CV= 1.3% Level 144 U/L CV= 0.9% Level 262 U/L CV= 0.6% **Total** Level 57 U/L CV= 4.4% Level 144 U/L CV= 3.8% Level 262 U/L CV= 2.9%	**Within run** Level 87.5 U/L CV= 0.5% Level 229 U/L CV= 0.7% Level 43.1 U/L CV= 0.6% Level 190 U/L CV= 1.2% **Total** Level 90.0 U/L CV= 1.0% Level 229 U/L CV= 0.8% Level 53.2 U/L CV= 0.8% Level 195 U/L CV= 0.9%
Method comparison	y= 1.025 x – 1 U/L r= 0.998 range: 18 to 1005 U/L	y= 1.008 x – 2.207 U/L r= 1.000 range: 32 to 828 U/L
Limitations	**Hemoglobin:** No significant interference up to 500 mg/dL. **Triglycerides:** No significant interference up to 3141 mg/dL. **Unconjugated bilirubin:** No significant interference up to 30.0 mg/dL (513 µmol/L). **Conjugated bilirubin:** No significant interference up to 29.5 mg/dL (504 µmol/L). **Ascorbic acid:** No significant interference up to 20.0 mg/dL. **Acetaminophen:** No significant interference up to 30.0 mg/dL. **Acetylsalicylic acid:** No significant interference up to 200.0 mg/dL.	**Hemoglobin:** No significant interference up to an H Index of 250 (approximate 250 mg/dL). **Lipemia (Intralipid):** No significant influence up to an L index of 2000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration. **Icterus:** No significant influence up to I Index of 60 (approximate conjugated and unconjugated bilirubin concentration of 60 mg/dL (1026 µmol/L)).
Calibration Frequency	1 day	5 days
On board stability	1 day	10 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): Roche Calibrator f.a.s.
Controls	Recommended quality control material (not included): ELITech Clinical Systems ELITROL I (Normal control) ELITech Clinical Systems ELITROL II (Pathologic control)	Recommended quality control material (not included): Roche Precinorm U Roche Precipath U

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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DEC 2 9 2011

Re: k113269
Trade Name: ELITech Clinical Systems ALP IFCC SL
Regulation Number: 21 CFR §862.1050
Regulation Name: Alkaline Phosphatase or Isoenzymes Test System
Regulatory Class: Class II
Product Codes: CJE
Dated: December 13, 2011
Received: December 22, 2011

Dear Ms. Hutson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K113269

Device Name: ELITech Clinical Systems ALP IFCC SL

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113269